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Date Mailed: November 24, 2004

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the application of

LANDOLFI, et al.

Application Serial No. 10/774,076

Filed: February 6, 2004

Title: AMPHIREGULIN ANTIBODIES  
AND THEIR USE TO TREAT CANCER  
AND PSORIASIS

Examiner: Chaudhuri, Aniruddho Ray

Group Art Unit: 1644

Attorney's Docket No.  
05882.0064.NPUS01

Confirmation No.: 7347

**Information Disclosure Statement**

**MS AF**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed;
  - ☐ a. Within three months of the U.S. filing date of a national application other than a continued prosecution application under §1.53(d);
  - ☐ b. Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
  - c. Before the mailing date of a first Office Action on the merits;
  - ☐ d. Before the mailing of a first Office Action after filing of a request for continued examination under § 1.115.

No statement under 37 C.F.R. § 1.97(e) or fee is required.

or;

- ☐ 2. This Information Disclosure Statement is being filed after the period specified in paragraph 1(a)-1(d) above, but before the mailing date of a Final Rejection or Notice of Allowance, or action that otherwise closes prosecution in the application, and
  - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
  - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2), or

- ☐ c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but on or before payment of the Issue Fee. Attached is our Check in the amount of \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(i), and
  - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
  - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

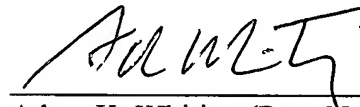
☐ 8. Copies of the documents were cited by or submitted to the Office in Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 08-3038 referencing docket number 05882.0064.NPUS01.

Respectfully submitted,

Date: November 24, 2004



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<b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary) <b>PTO FORM 1449</b>	ATTY. DOCKET NO.	APPLICATION NO.
	05882.0064.NPUS01	10/774,076
	APPLICANT	
	Landolfi, et al.	
	FILING DATE	GROUP
	February 6, 2004	1644

U.S. PATENT DOCUMENTS								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	1.	5,115,096	05-19-92	Shoyab et al.				
	2.	5,262,298	11-03-93	Shipley et al.				
	3.	5,830,995	11-03-98	Shoyab et al.				
	4.	5,855,885	01-05-99	Chiswell et al.				
	5.	6,204,359	03-20-01	Delaey, et al.				
	6.	20020156263 A1	10-24-02	Chen				
FOREIGN PATENT DOCUMENTS								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	7.	EP 1 074 617	02-07-01	Europe				
	8.	EP 1 249 237 A1	10-16-02	Europe				
	9.	WO 01/70979	09-27-01	PCT				
	10.	WO 01/70984	09-27-01	PCT				
	11.	WO 01/96389	12-20-01	PCT				
	12.	WO 02/10449	02-07-02	PCT				
	13.	WO 02/41763	05-30-02	PCT				
	14.	WO 02/057414	07-25-02	PCT				
	15.	WO 02/074979	09-26-02	PCT				
	16.	WO 02/077234	10-03-02	PCT				
	17.	WO 02/085298	10-31-02	PCT				
	18.	WO 02/092000	11-21-02	PCT				
	19.	WO 03/008583	01-30-03	PCT				
	20.	WO 03/014159	02-20-03	PCT				
	21.	WO 03/022222	03-20-03	PCT				
	22.	WO 90/14069	11-29-90	PCT				
	23.	WO 96/12019	04-25-96	PCT				
	24.	WO 97/23507	07-03-97	PCT				

<b>LIST OF REFERENCES CITED BY APPLICANT</b> <i>(Use several sheets if necessary)</i>  <b>PTO FORM 1449</b>	ATTY. DOCKET NO.	APPLICATION NO.
	<b>05882.0064.NPUS01</b>	<b>10/774,076</b>
	APPLICANT	
	<b>Landolfi, et al.</b>	
	FILING DATE	GROUP
	<b>February 6, 2004</b>	<b>1644</b>

25.	WO 99/38972	08-05-99	PCT				
<b>OTHER REFERENCES</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
26.	Communication Relating to the Results of the Partial International Search in PCT/US2004/004176						
27.	Cook et al., "A heparin sulfate-regulated human keratinocyte autocrine factor is similar or identical to amphiregulin," Mol. Cell. Biol., 11, 2547-2557 (1991)						
28.	Cook et al., "Inhibition of autonomous human keratinocyte proliferation and amphiregulin mitogenic activity by sulfated polysaccharides," In Vitro Cell. Dev. Biol. 28A, 218-222 (1992)						
29.	Cook, et al., "Amphiregulin Messenger RNA Is Elevated in Psoriatic Epidermis and Gastrointestinal Carcinomas," Cancer Res. 52: 3224-3227 (1992)						
30.	Cook, et al., "Overexpression of amphiregulin in the epidermis of transgenic mice induces a psoriasis-like cutaneous phenotype," J. Invest. Dermatol. 113(5): 860 (Nov. 1999).						
31.	Cook, et al., "Transgenic Expression of the Human Amphiregulin Gene Induces a Psoriasis-like Phenotype," J. Clin. Invest. 100: 2286-2294 (1997)						
32.	Damstrup, et al., "Amphiregulin acts as an autocrine growth factor in two human polarizing colon cancer lines that exhibit domain selective EGF receptor mitogenesis," British Journal of Cancer 80(7): 1012-19 (June 1999)						
33.	Johnson, G. R., et al., "Amphiregulin induces tyrosine phosphorylation of the epidermal growth factor receptor and p185erbB2. Evidence that amphiregulin acts exclusively through the epidermal growth factor receptor at the surface of human epithelial cells," J. Biol. Chem. 268: 2924-2931 (1993)						
34.	Piepkorn et al., "Amphiregulin-dependent proliferation of cultured human keratinocytes: autocrine growth, the effects of exogenous recombinant cytokine, and apparent requirement for heparin-like glycosaminoglycans," J. Cell. Physiol. 159, 114-120 (1994)						
35.	Piepkorn, et al., "Autocrine Regulation of Keratinocytes: the Emerging Role of Heparin-Binding, Epidermal Growth Factor-Related Growth Factors," J. Invest. Dermatol. 111(5):715-721 (Nov. 1998)						
36.	Piepkorn, et al., "Overexpression of amphiregulin, a major autocrine growth factor for cultured human keratinocytes, in hyperproliferative skin diseases," Am. J. Dermatol. 18: 165-171 (1996)						
37.	Plowman et al., "The amphiregulin gene encodes a novel epidermal growth factor-related protein with tumor-inhibitory activity," Mol. Cell. Biol. 10, 1969-1981 (1990)						
38.	Shoyab et al., "Amphiregulin: a bifunctional growth-modulating glycoprotein produced by the phorbol 12-myristate 13-acetate-treated human breast adenocarcinoma cell line MCF-7," Proc. Natl. Acad. Sci. USA 85, 6528-6532 (1988)						
39.	Shoyab et al., "Structure and Function of Human Amphiregulin: A Member of the Epidermal Growth Factor Family," Science 243, 1074-1076 (1989)						
40.	Thompson, S.A., et al., "COOH-terminal extended recombinant amphiregulin with bioactivity comparable with naturally derived growth factor," J. Biol. Chem. 271(30): 17927-31 (1996)						